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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,791	07/25/2003	Steve Bigus	ACS 64940 (2238D)	2675

24201 7590 02/03/2006

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,791	BIGUS ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11 and 20-34* is/are pending in the application.

4a) Of the above claim(s) *8-10,22,23 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,11,20,21 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Preliminary Amendment filed July 25, 2003 has been entered. The changes to the specification and claims have been approved by the examiner. Claims 2-4 and 12-19 have been canceled, and new claims 20-34 have been added.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because it does not contain a specific reference to the (preliminary) amendment filed on date with the application. Applicant must file a supplemental declaration under 37 CFR 1.63 containing the proper averment under 37 CFR 1.63(b)(2) referring to the amendment. See MPEP § 608.04(b) and § 714.01(e).

Election/Restrictions

3. Applicant's election without traverse of Species 6, Figures 9 and 10 (biocompatible material in the form of a filament) and claims 1, 5-11, 20-31 and 33 in the reply filed on January 19, 2006 is acknowledged.

4. In addition to the claims withdrawn by the applicant, the examiner further withdraws claims 8-10, 22 and 23 for being directed to non-elected Species 7-9 (biocompatible material in the form of a coating) of Figures 12a-13b. The examiner also withdraws claims 31 and 33 for being directed to non-elected Species 1-5 (biocompatible material in the form of a sheath) of

Figures 3-8b. Because a coating is not shown in Figures 9 and 10, and Figures 9 and 10 are not described in the specification as having a coating, there is no reason to assume that there is a coating. The examiner does not agree with applicant's reasoning that there might be a coating simply because claim 1 is held as generic. The "biocompatible material" of claim 1 can be referring to any one of the sheath, filament and coating configurations disclosed in the specification and shown in the drawings. Because applicant has elected the patentably distinct species of the filament, all claims directed to non-elected species are withdrawn. Claims 1, 5-11 and 20-34 are currently pending, of which claims 8-10, 22, 23 and 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. The claims being considered for further examination on the merits are claims 1, 5-7, 11, 20, 21 and 24-30.

Information Disclosure Statement

5. The Information Disclosure Statement filed July 25, 2003 has been entered. All cited references have been considered. An initialed and signed copy of the IDS is enclosed.

Drawings

6. The drawings are objected to because reference number "30" in Figure 10 is not directed to a "sidearm" (see page 9, line 11). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number

of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities:

a) The first sentence of the specification regarding related applications must be updated to indicate that 09/897,743 is now U.S. Patent No. 6,629,992, and that 09/897,743 is a continuation-in-part of 09/632,741, now abandoned.

b) On page 9, line 11, "10 The" should be changed to --10. The--.

c) On page 16, line 24, "guidewire 24" should b changed to --guidewire 20--.

Appropriate correction is required.

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 1 requires that the "biocompatible material is configured to fail at an

inflation pressure *below the nominal inflation pressure of the expandable member*" (italicized for emphasis). According to page 13, lines 7-9 of the specification, "the filament 70 may be configured to fail as pressure is applied, as where the balloon 24 is expanded to force the stent 14 to expand against the restraint of the filament". According to page 13, lines 21-23 of the specification, when "the balloon is pressurized during stent deployment, the heat bonding will fail, causing the filament to loosen its hold on the stent and permitting the stent to expand". Neither of these statements nor any other in the specification provides support for the specification limitation of the biocompatible material being configured to fail at an inflation pressure *below the nominal inflation pressure of the expandable member*. Because this limitation was claimed in a preliminary amendment filed on date with the application, it is not considered new matter. However, it must now be included into the specification. Because this limitation is not supported by the either of the parent applications 09/897,743 and 09/632,741, claim 1 and claims dependent thereon do not receive priority benefit of the parent applications. Claims 1, 5-7, 11, 20, 21 and 24 have an effective filing date of July 25, 2003.

The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter of new claim 25. Claim 25 requires that the filament be wrapped around and heat bonded to the stent "such that it does not overlie the distal end and the proximal end of the stent". Because this limitation was claimed in a preliminary amendment filed on date with the application and is supported by a broad interpretation of Figures 9 and 10, it is not considered new matter. However, it must now be included into the specification. Claims 25-30 receive priority benefit of parent application 09/897,743 and have an effective filing date of June 29, 2001.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 5, 6, 11 and 24 rejected under 35 U.S.C. 102(e) as being anticipated by Lenker (USPN 6,878,161).

Lenker ('161) discloses a catheter assembly for delivering an endoprosthesis within a body lumen with all the elements of claim 1. See Figures 1A-2C for a catheter (126) and an endoprosthesis (110) disposed on an expandable member (125). See Figure 1A and column 6, lines 17-31 and 65-67 for a biocompatible material (123) being positioned on the endoprosthesis (110) and preventing expansion of the endoprosthesis (110). See column 7, lines 4-20 for the biocompatible material (123) being configured to fail at an inflation pressure below the nominal inflation pressure of the expandable member (125).

Claim 5, see Figure 1A and column 6, lines 20-22 for the biocompatible material (123) comprising a filament that is wrapped around at least a portion of the endoprosthesis (110).

Claims 6 and 11, see Figure 1A and column 6, lines 20-22 for the endoprosthesis having an open lattice configuration with open areas, and the filament being threaded through the open areas. At least a portion of the filament is therefore positioned within the open areas.

Claim 24, see column 5, lines 58-67 for the endoprosthesis comprising a self-expanding stent. See Figure 1A and column 6, lines 65-67 for the biocompatible material (123) providing an inward pressure on the stent to prevent expansion of the stent.

11. Claims 25, 26, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenker et al. (USPN 5,843,158).

Lenker et al. ('158) disclose an endoprosthesis for deployment in a body lumen with all the elements of claim 25. See Figures 5B-5D and column 9, lines 36-53 for a stent (100) and a biocompatible material comprising a filament (102) wrapped around and heat bonded (column 9, lines 44) to the stent (100) such that it does not overlie the distal and proximal ends of the stent (100) and prevents expansion of the stent (100).

Claim 26, see column 9, line 44 for tying of the filament (102), which comprises feeding the filament through the open areas.

Claim 29, See Figures 5-5D for the stent (100) having an open-lattice structure.

Claim 30, see column 8, lines 42-43 for the frame rings (72) making up the stent (100) being self-expanding. See column 4, lines 20-25 and column 9, lines 39-42 for the filament (102) providing inward pressure on the stent (100) to prevent expansion of the stent (100).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker ('161) in view of Lenker et al. ('158).

Lenker ('161) discloses a catheter assembly for delivering an endoprosthesis within a body lumen with all the elements of claim 5, but is silent to the filament being heat bonded to the endoprosthesis, as required by claim 7. Lenker et al. ('158) teach a frangible filament (102) that is wrapped around and heat bonded to an endoprosthesis (100) in order to attach the filament to the endoprosthesis. See column 9, lines 42-45. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lenker et al. ('158) to modify the assembly of Lenker ('161) by having the filament (123) heat bonded to the endoprosthesis (110) in order to attach the filament to the endoprosthesis. The examiner contends that heat bonding will advantageously prevent the filament from becoming detached from the endoprosthesis and becoming loose in the blood stream upon failing.

14. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker ('161) in view of Lenker et al. ('158) and Solar (USPN 5,549,635, as cited in applicant's IDS).

Lenker ('161) discloses a catheter assembly for delivering an endoprosthesis within a body lumen with all the elements of claim 5, but is silent to the filament comprising areas of varying strength along the filament such that the filament fails in a controlled manner, as required by claim 20, and of the areas of varying strength consisting of one of scoring, perforations and thinner diameter portions, as required by claim 21. Lenker et al. ('158) teach a

frangible filament (102) that is wrapped around and heat bonded to an endoprosthesis (100) in order to attach the filament to the endoprosthesis. Solar teaches an endoprosthesis delivering catheter assembly, wherein a biocompatible material (40) is positioned on the endoprosthesis (10) and is configured to fail upon expansion of the expandable member (38). The biocompatible material (40) includes areas of varying strength in the form of perforations (42) in order for the biocompatible material (40) to fail only at those areas with the perforations and prevent the remaining portions of the biocompatible material (40) from being torn away from attachment to the expandable member (38). See Figures 4a-4c and column 6, lines 50-54 and column 7, lines 10-22. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lenker et al. ('158) and Solar to modify the filament (123) of Lenker ('161) by heat bonding the filament (123) to the endoprosthesis and including perforations. Upon inflation of the expandable member (125), the filament (123) will fail only at those areas with the perforations while the remaining portions of the filament (123) that are heat bonded to the endoprosthesis (110) will be prevented from being torn away and becoming loose in the blood stream.

15. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. ('158) in view of Solar.

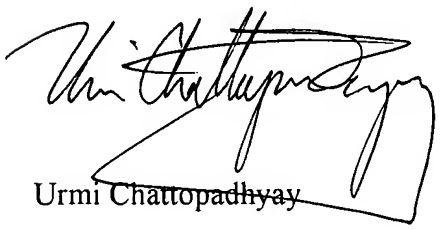
Lenker et al. ('158) disclose an endoprosthesis for deployment in a body lumen with all the elements of claim 25, but are silent to the filament comprising areas of varying strength along the filament such that the filament fails in a controlled manner, as required by claim 27, and of the areas of varying strength consisting of one of scoring, perforations and thinner diameter

portions, as required by claim 28. Solar teaches an endoprosthesis delivering catheter assembly, wherein a biocompatible material (40) is positioned on the endoprosthesis (10) and is configured to fail upon expansion of the expandable member (38). The biocompatible material (40) includes areas of varying strength in the form of perforations (42) in order for the biocompatible material (40) to fail only at those areas with the perforations and prevent the remaining portions of the biocompatible material (40) from being torn away from attachment to the expandable member (38). See Figures 4a-4c and column 6, lines 50-54 and column 7, lines 10-22. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Solar to modify the filament (102) of Lenker et al. ('158) by including perforations in order for the filament (102) to fail only at those areas with the perforations while the remaining portions of the filament (102) that are heat bonded to the stent (100) are prevented from being torn away and becoming loose in the blood stream.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

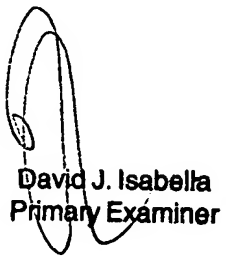
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner